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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,149	11/01/2000	William F. Swain	APF 34.20	4573

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EXAMINER
LI, BAO Q

ART UNIT	PAPER NUMBER
1648	13

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/705,149	SWAIN ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communicati n appears on the cover sheet with th correspond nc address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/09/2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 35-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-51 are pending.

Response to Amendment

This is a response to the amendment, paper No. 8, filed 10/09/02. Claims 15, 17 and 26 have been amended. Claims 15-34 are considered before the examiner.

This application contains claims 1-14 and 35-51 drawn to an invention non-elected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

Claims 15-34 are still rejected under 35 U.S.C. 112, second paragraph on the same ground as stated in the previous Office Action, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15, 19 and 28 are still rejected for using a relative term of "derived".

Applicants argue that the claim must be analyzed in light of the content of the disclosure in the specification, accordingly, the rejection should be withdrawn.

Applicants' argument has respectfully considered; however, it is not found persuasive because the limitation described in the specification cannot read into the claim. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants are suggest to amend claim by using more defined language to overcome the rejection.

In response to the rejection of undefined "particle-mediated transdermal delivery, Applicants argue that specification does have an expression on page 19, 33 through 35, the rejection should be withdrawn. Applicants' argument has been fully considered; however it is not found persuasive because Applicants are reminded that claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Is viral like particle intended or protein particle is intended? This affects the dependent claims 16-34.

Claim 15 is still vogue and indefinite in that the metes and bonds of " an amount sufficient" are not defined. Applicants argue that specification does have an expression on page 19, 33 through 35, the rejection should be withdrawn. Applicants' argument has been fully considered; however it is not found persuasive because the limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This affects the dependent claims 16-34 too.

Claims 19 and 28 are still rejected for recitation of unclear the vector construct comprises at least one pathogen.

Applicants argue that the claim call for the inclusion of genomic fragment of 5 kilobases in size, one ordinary skill person should understand.

Applicant's argument has been fully considered; however, it is not found persuasive because the limitation of a kilobases is not in the claim. Furthermore, the claim should point out what the upper limitation of the pathogen is intended in the said claim.

Applicants further argue that the anticipation rejection is improper because the claim 19 and 28 are dependent on claim 15.

Applicants' argument has been fully considered; however, it is not found persuasive because the claims 19 and 28 are recited the pathogen in claims 17 or 26. If the claims are dependent claims of claim 15, the claims should be amended like this: the pathogen of claim 15 but not claim 17 or 26 because plasmid or cosmid are pathogens too. This affects the dependent claims 19 and 29-30.

Claims 21 and 30 are still rejected for recitation of "more than one virus", which fails to define what is the up-limitation of the intended composition is.

Applicants argue that the reasonable explanation calls for the inclusion of genomic fragment of 5 kilobases in size, one ordinary skill person should understand.

Applicant's argument has been fully considered; however, it is not found persuasive because the limitation of a kilobases is not in the claim. Furthermore, the claim should point out what the upper limitation of the pathogen is intended in the said claim.

Claims 22 and 31are still vague an indefinite in that the metes and bonds of the cited "a density sufficient" are not defined.

Applicants argue that the specification has an explanation, accordingly, the rejection should be withdrawn.

Applicants' argument has been respectfully considered; however, it is not found persuasive because the limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).This affects the dependent claim 23.

Claims 23 and 32 are still vague and indefinite in that the metes and bonds of " a metal" are not defined.

Applicants argue that the specification has explained for the suitable metal, accordingly, the rejection should be withdrawn.

Applicants' argument has been respectfully considered; however, it is not found persuasive because the limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 112

Claims 15-34 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, because the specification, while being enabling for a method for using a vector DNA coated with gold particle carrying only one antigen of a HSV glycoprotein D to induce an immune response in animal, does not reasonably provide enablement for a method for using any vector DNA-coated with any metal carrying more than one antigen from more than one pathogenic viruses to induce an immune response in animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that Applicants have provide more than sufficient disclosure regarding how to make and use their composition and have explained this disclosure with working examples. The skilled artisan would thus have no difficulty in following applicants' directions to test other compositions for their ability to practice an immune response in a suitable subject.

Applicants' argument has been respectfully considered, Office is agreed with the most part of the argument; however, it is not persuasive because the scope of read broadly on any or

all metal coated DNA structure. But there is no example of using other metal for coating the claimed DNA construct that is used for inducing an immune response.

It is well known that not every metal can be used in vivo because of the toxicity of some metals. Therefore, Applicants are suggested to amend the claim to the gold metal as it is disclosed in the specification to overcome the rejection. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 15-19, 22-25 and 31-34 are still rejected under 35 U.S.C. 102(a) on the same ground as stated in the previous Office Action, as being anticipated by Braun et al. (Virology, 1999, Vol. 265, pp. 46-45).

Applicants argue that Braun et al. clearly fails to anticipate the current Application because it fails to provide the vector construct containing genomic fragment " greater than 5 kilobases in size.

Applicants' argument has been fully considered; however, it is not found persuasive because Braun et al disclose the same method of using a metal coated vector construct carrying an antigen of glycoprotein D of the Bovine herpesvirus-1 antigen to induce an immune response against glycoprotein D of the Bovine herpesvirus-1. This has same disclosure as taught by the specification of current Application of delivering a DNA-coated gold particle in which the plasmid encodes one HSV antigen gD.

Patent Office is not the lab, which has a facility to test the size of the glycoprotein as disclosed in the prior art. According to the art, glycoprotein of bovine herpesvirus has similar size to the glycoprotein D of human herpesvirus, therefore, the inherently has same structural characteristics. The rejection is maintained.

Claims 15, 17-19, 22-28, 31-34 are still rejected under 35 U.S.C. 102(a) on the same ground as stated in the previous Office Action, as being anticipated by Tacket et al. (Vaccine 1999, Vol. 17, pp. 2826-2829).

Applicants argue that Tacket et al. clearly fails to anticipate the current Application because it fails to provide the vector construct containing genomic fragment " greater than 5 kilobases in size.

Applicants' argument has been fully considered; however, it is not found persuasive because Tacket et al. disclose a same method of using a same metal particle-mediated DNA immunization delivered by a particle mediated transdermal delivery system, Powderjet XR1 onto the skin of the human induce a booster response against HBsAg (See entire document). The metal is gold, the core particle is a vector DNA construct, which carries a viral antigen. Therefore, they meet all limitation of the claimed invention. Regarding tot he DNA size, Patent Office is not the lab, which has a facility to test the size of the DNA particle as disclosed in the prior art.

Claims 15, 17-19, 22-28, 31-34 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action, as being anticipated by Lodmell et al. (Vaccine 1998, Vol. 16, pp. 115-118).

Applicants argue that Lodmell et al. clearly fails to anticipate the current Application because it fails to provide the vector construct containing genomic fragment " greater than 5 kilobases in size.

Applicants' argument has been fully considered; however, it is not found persuasive because Lodmell et al. disclose a same method of using a metal particle-mediated DNA immunization delivered by a particle mediated transdermal delivery system, Accell®-gene delivery system onto the skin of mice to induce a immune response against viral antigen of glycoprotein G (See entire document). The metal is gold, the core particle is a vector DNA construct encoding a viral antigen. Therefore, they meet all limitation of the claimed invention. Regarding tot he DNA size, Patent Office is not the lab, which has a facility to test the size of the DNA particle as disclosed in the prior art. The rejection is maintained.

Claims 15, 17-19, 22-28, 31-34 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Haynes et al. (AIDS Research and Human Retroviruses 1994, Vol. 10, pp. S43-S45).

Applicants argue that Haynes et al. clearly fails to anticipate the current Application because it fails to provide the vector construct containing genomic fragment " greater than 5 kilobases in size.

Applicants' argument has been fully considered; however, it is not found persuasive because Haynes et al. disclose a same method of using a metal particle-mediated DNA

immunization delivered by a particle mediated transdermal delivery system, Accell®-gene delivery system onto the skin of mice to induce a immune response against viral antigen of HIV-gp160 and gp120 (See entire document). The metal is gold, the core particle is microsizes gold particle of a vector DNA construct encoding a viral antigen. Therefore, they meet all limitation of the claimed invention. Regarding tot he DNA size, Patent Office is not the lab, which has a facility to test the size of the DNA particle as disclosed in the prior art. The rejection is maintained.

Claims 15, 17-19, 22-28, 31-34 are still rejected under 35 U.S.C. 102(b) on the previous Office Action as being anticipated by Webster et al. (Vaccine 1994, Vol. 12, pp. 1495-1498).

Applicants argue that Webster et al. clearly fails to anticipate the current Application because it fails to provide the vector construct containing genomic fragment " greater than 5 kilobases in size.

Applicants' argument has been fully considered; however, it is not found persuasive because the Webster teach a metal coated vector construct is gold coated plasmid DNA expresses an influenza virus haemogglutinin and IL-2 of a vector DNA construct encoding a viral antigen. Patent Office is not the lab, which has a facility to test the size of the DNA particle as disclosed in the prior art. The rejection is maintained.

Claims 15, 17-19, 22-28, 31-34 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Macklin et al. (Journal of Virology 1998, Vol. 72, pp. 1491-1496).

Applicants argue that Macklin et al. clearly fails to anticipate the current Application because it fails to provide the vector construct containing genomic fragment " greater than 5 kilobases in size.

Applicants' argument has been fully considered; however, it is not found persuasive because Macklin et al. teach a metal coated DNA vector construct is gold coated plasmid DNA vector carrying a viral antigen of influenza virus HA protein to induce an immune response. Patent Office is not the lab, which has a facility to test the size of the DNA particle as disclosed in the prior art. The rejection is maintained.

Claims 15, 17-19, 22-28, 31-34 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action, as being anticipated by Fynan et al. (P.N.A.S. U.S.A. 1993, Vol. 90, pp. 11478-11482).

Applicants argue that Fynan et al. clearly fails to anticipate the current Application because it fails to provide the vector construct containing genomic fragment " greater than 5 kilobases in size.

Applicants' argument has been fully considered; however, it is not found persuasive because Fynan et al. teach a metal coated DNA vector construct is gold coated plasmid DNA vector carrying a viral antigen of influenza virus HA1 protein to induce an immune response. Patent Office is not the lab, which has a facility to test the size of the DNA particle as disclosed in the prior art. The rejection is maintained.

Claims 15, 17-19, 22-28, 31-34 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action, as being anticipated by Johnston et al. (US Patent No. 6,1694,389B1).

Applicants argue that Johnston et al. clearly fails to anticipate the current Application because it fails to provide the vector construct containing genomic fragment " greater than 5 kilobases in size.

Applicants' argument has been fully considered; however, it is not found persuasive because method disclosed by Johnston et al. is also related to delivery a metal coated DNA vector construct transdermally into a host for inducing an immune response. The DNA vector is coated by a metal, gold that carrying a gene, wherein the gene can be an antigen. Patent Office is not the lab, which has a facility to test the size of the DNA particle as disclosed in the prior art. The rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 15-34 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (US Patent 6,1694,389B1), Braun et al. (Virology 1999, Vol. 265, pp. 46-56), Stanberry et al. (J. Infect. Dis. 1987, Vol. 155, pp. 156-163), Pertmer et al. (Vaccine 1995, Vol. 15, pp. 1427-1430) and Barry et al. Vaccine 1997, Vol. 15, pp. 788-791) on the same ground as stated in the previous Office Action.

Applicants argue that none of the reference cited by Office teach or suggest that the construct containing a genomis fragment having a greater than 5 kilobases in size. Since there I no suggestion or motivation of making the modification of the claimed product regarding to this size limitation, the rejection should be withdrawn.

Applicants' argument has been fully considered; however, it is not found persuasive because method disclosed by prior art meet all limitation of the claimed invention. For example, all prior art cited by the Previous Office Action is related to a metal, gold coated vector DNA construct that encodes a viral antigen, some of the antigen has similar size as it is disclosed in the current application, for example, glycoprotein of herpesvirus. There is no suggestion that the DNA particle is less than 5 kilobases in size. Lots of eukaryotic vector or plasmid DNA is able to carry a large size of the insert. For example, cosmid DNA can insert 35-45 kb whereas HSV-1 is about 152 kb. YAC enables cloning of inserts of up to 1 megabase and PAC P1 base vector can accept inserts in the 70-100 kb range of insertion.

The use of a gene gun for delivering a DNA-coated gold particles carrying an pathogenic antigen onto the skin of a mammal to induce an immune response is also well known in the art as evidenced by so many prior art cited supra.

As stated in the previous Office Action, the method for using the gene gun for delivering a DNA-coated particle loaded with a DNA plasmid for inducing an immune response is well established method with more efficient effect and economic beneficial, the modification of the plasmid carrying more than one antigens either from same pathogenic virus or from different pathogenic viruses in a certain size is generally recognized as being within the level of the ordinary skill in the art, since most available antigens used in the art are all well characterized too unless Applicant point out the size of the antigens used for the claimed invention are an unexpected result over other DNA particle which has a size less than 5 kilobases. See In re Rose, 105 USPQ 237 (CCPA 1995) because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the workable ranges involves only routine skill in the art, In re Aller, 105, USPQ 233.

Hence, the claimed invention is as whole a prime facie case obvious without any unexpected result.

Conclusion

No claimed are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
November 29, 2002

James C. Housel
JAMES HOUSEL 12/2/02
SUPERVISORY PATENT EXAMINER
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